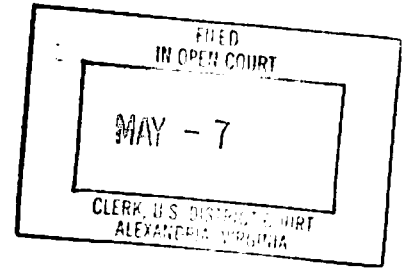


UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA

Alexandria Division



UNITED STATES OF AMERICA

v.

HANOCH DAVID STEIN,
Defendant

Criminal No. 1:14-cr-397-5

STATEMENT OF FACTS

The United States and the defendant, HANOCH DAVID STEIN, agree that the following facts are true and correct, and that had this matter proceeded to trial, the United States would have proven them beyond a reasonable doubt with admissible and credible evidence:

The Conspiracy

1. Beginning in at least April 2011, and continuing until the present, in the Eastern District of Virginia and elsewhere, defendant HANOCH DAVID STEIN, together with co-conspirators including TC MEDICAL GROUP, SB MEDICAL INC., DAVID E. BURKE, a/k/a "David Johnson," TZVI LEXIER, ASAF AKIVA IBRAHIMIAN, a/k/a "Adam Darius," and REUVEN MIRLIS, a/k/a "Daniel Mirl," and other individuals including co-conspirators based in Canada, including R.L. and S.R., co-conspirators in Germany, including C.G., and co-conspirators in the United States, including A.T. in Baltimore, Maryland; R.R. and M.R. in Lakewood, New Jersey; S.M. and E.M. in Edison, New Jersey; and A.B. in Boynton Beach, Florida, engaged in a conspiracy to smuggle into and distribute within the United States, including within the Eastern District of Virginia, misbranded prescription drugs and devices.

2. Defendants TC MEDICAL GROUP and SB MEDICAL INC. were corporations based in Barbados and Canada, respectively. TC MEDICAL GROUP and SB MEDICAL INC.,

together with co-conspirators specialized in the illegal importation from abroad and wholesale distribution within the United States of misbranded prescription drugs and devices. TC MEDICAL GROUP and SB MEDICAL INC. caused to be shipped from abroad orthopedic injections, rheumatology infusions, cosmetic devices, optomology products, and oncology drugs either directly to customers or to locations, including the personal residences and mailboxes of co-conspirators serving as individual drop shippers located in Maryland, New Jersey, Florida, Connecticut, and Arlington, Virginia, in the Eastern District of Virginia. TC MEDICAL GROUP and SB MEDICAL INC. used these individual drop shippers to receive, repack, and re-send these drugs and devices to customers throughout the United States, including the Eastern District of Virginia, and to receive check payments by mail, including from the Eastern District of Virginia, all to give the false impression that the drugs and devices were FDA-approved for sale in the United States. TC MEDICAL GROUP and SB MEDICAL INC. operated under other names, including Premium Pharmaceuticals, Clinic Care Direct, Orthodocspharm, and Premium Drug Care, and under websites including www.tcmedicalgroup.com, www.tcmedgroup.com, www.ccaredirect.com, and www.premiumpharmaceuticals.com.

3. Specifically, members of the conspiracy did knowingly and intentionally combine, conspire, confederate, and agree, with each other and with other persons, to: (a) defraud the United States and its agencies by: impeding, impairing, and defeating the lawful functions of the Food and Drug Administration ("FDA") to protect the health and safety of the public by ensuring that prescription drugs and devices distributed in the United States were safe and effective from the time of manufacturing to the delivery to the entity that sold or dispensed the product to the ultimate consumer or patient; and impeding, impairing, and defeating the lawful functions of Customs and Border Protection ("CBP") and Immigration and Customs

Enforcement—Homeland Security Investigations (“ICE-HSI”) to protect the public health and safety by governing the importation into the United States of goods and merchandise, including drugs and devices, through deceitful and dishonest means; (b) fraudulently and knowingly import and bring into the United States merchandise contrary to law, and receive, conceal, buy, sell, or in any manner facilitate the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law; (c) introduce into interstate commerce misbranded prescription drugs and devices; and (d) knowingly engage in the wholesale distribution in interstate commerce of prescription drugs in the United States, including to the Commonwealth of Virginia without being licensed to do so.

4. From approximately April 2011 through December 3, 2014, the co-conspirators, including defendant HANOCH DAVID STEIN, illegally imported and distributed misbranded prescription drugs and devices within the United States, amounting to, or exceeding, \$33,634,452.75, in gross proceeds. Of these gross proceeds, at least \$13,748,603.00 were attributable to drugs and devices that Stein received, stored, and shipped.

5. Specifically, the conspiracy of which defendant HANOCH DAVID STEIN was a part, smuggled and sold misbranded prescription drugs and devices in the United States, including in the Eastern District of Virginia, with intent to defraud and mislead, in the following manner:

a. Beginning in or around April 2011, members of the conspiracy purchased from co-conspiring foreign suppliers prescription drugs and devices manufactured and labeled for use in foreign countries, including the Republic of Turkey, Canada, France, Italy, the United Kingdom, and other countries, and caused them to be shipped into the United States.

b. Foreign suppliers, based mostly in the United Kingdom, obtained prescription drugs and devices from yet other foreign countries. Those foreign suppliers in turn forwarded them, at the direction of members of the conspiracy, to doctors and medical practices in the United States, or alternatively to locations including the personal residences and mailboxes of co-conspiring individual drop shippers in Maryland, New Jersey, Florida, Connecticut, and Arlington, Virginia, in the Eastern District of Virginia.

c. Drop shippers in the United States regularly received packages of prescription drugs and devices from abroad, removed labels and other indicia showing that they had been imported from abroad, repacked the orders, and re-shipped them to doctors and medical practices throughout the United States, including to the Eastern District of Virginia, to give the false impression that the drugs were being distributed domestically and legally.

d. To impede, impair, and defeat the lawful functions of the FDA, CBP, and ICE-HSI, the defendants, together with other co-conspirators, engaged in deceitful and dishonest means, including: (i) breaking up large shipments of prescription drugs and devices into smaller separate packages to be sent into the United States to multiple locations, under multiple names, over multiple days, to be consolidated upon arrival after evading border detection; (ii) shipping packages via Royal Mail and Parcelforce Worldwide, which—because they were United Kingdom-based services—allowed packages to be delivered through the United States Postal Service with less scrutiny than would be applied to packages arriving from other countries; (iii) including on customs forms misleading statements about the package contents, weight, and value, and addressing packages to co-conspirators under false names and/or titles; (iv) frequently mishandling prescription drugs subject to strict temperature requirements by failing to keep them at a consistent temperature during shipping and storage as required for the drug's safe and

effective use; and (v) failing to keep and provide the appropriate pedigree records to prove or track the proper shipping, storage, and transaction history of prescription drugs through the supply chain.

e. Defendant HANOCH DAVID STEIN, together with co-conspirators, used the personal residences and mailboxes of drop shippers in the United States to receive payment checks mailed from United States customers, including from the Eastern District of Virginia, to give the false impression that TC MEDICAL GROUP and SB MEDICAL INC. and their affiliates were based in the United States. Drop shippers in the United States did not cash the payment checks but instead forwarded the checks received to TC MEDICAL GROUP in Canada.

f. Members of the conspiracy internally tracked prescription drugs and devices for sale in the United States by their true origin, by for example, separately tracking the sales of “Botox English” and “Botox, Allergan International”; “Lucentis English” and “Lucentis Turkish”; “Synvisc Classic Turkish” and “Synvisc classic”; “Hyalgan Italian Pack” and “Hyalgan”.

g. Members of the conspiracy regularly communicated with each other via email about the foreign acquisition, illegal importation, and sale of misbranded prescription drugs and devices in the United States.

6. Members of the conspiracy derived a financial benefit from the illegal importation and sale of misbranded prescription drugs and devices throughout the United States, including in the Eastern District of Virginia.

7. Members of the conspiracy, including defendant HANOCH DAVID STEIN, illegally imported or caused the importation and subsequent distribution of the following misbranded prescription drugs and devices:

Product	Use
Aclasta	Injectable drug used to treat osteoporosis (bone decay). Not FDA-approved for use in the United States. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Actemra	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation). Subject to FDA black-box warning: “[I]ncreased risk for developing serious infections that may lead to hospitalization or death.” Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light and moisture.
Artzal	Injectable device used to treat osteoarthritis (joint pain). Not FDA-approved for use in the United States.
Bonviva	Injectable infusion drug used to treat of osteoporosis (bone decay). Not FDA-approved for use in the United States.
Botox	Injectable prescription drug used to treat bladder disorders, chronic migraines, muscle spasms, and abnormal head positions. Subject to FDA black-box warning: “Swallowing and breathing difficulties can be life threatening and there have been reports of death.” Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Botox Cosmetic	Injectable prescription drug used to treat forehead wrinkles. Subject to FDA black-box warning: “Swallowing and breathing difficulties can be life threatening and there have been reports of death.” Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Dysport	Injectable prescription drug used to treat abnormal head positions and forehead wrinkles. Subject to FDA black-box warning: “Swallowing and breathing difficulties can be life threatening and there have been reports of death.” Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light.
Euflexxa	Injectable Class III prescription device used to treat osteoarthritis (joint pain). Must be kept away from light.
Hyalgan	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Juvederm	Injectable Class III prescription device used to treat facial wrinkles and folds. Juvederm 2, Juvederm 3, and Juvederm 4 are not FDA-approved for use in the United States.
Lucentis	Injectable prescription drug used to treat macular degeneration of the eye. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light.
Mabthera	Injectable prescription chemotherapy drug not FDA-approved for use in the United States. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from direct sunlight or shaking.
Macrolane	Injectable Class III device used for body contouring. Not FDA-approved for use in the United States.

Orencia	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation). Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light and freezing.
Orthovisc	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Prolia	Injectable prescription drug used to treat osteoporosis (bone decay). Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light, heat, and vigorous shaking.
Radiesse	Injectable Class III prescription device used to treat facial wrinkles and folds.
Remicade	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation), bowel inflammation, skeletal inflammation, skin inflammation, and other conditions. Subject to FDA black-box warning: "Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Restylane	Injectable Class III prescription device used to treat facial wrinkles and folds, lip-filler.
Supartz	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Synvisc	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Zometa	Injectable prescription drug used to treat complications associated with cancer.

8. The prescription drugs and devices smuggled and distributed by members of the conspiracy were misbranded because they failed to bear adequate directions for use in that they, among other things, (a) were not in the possession of a person, or his agents or employees, who was regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices; (b) failed to bear a label that contained the required language limiting their use to prescription only and for prescription drugs; (c) failed to bear the FDA-approved labeling and/or at any time before dispensing its label failed to bear, at a minimum, the "Rx only" symbol. The drugs and devices were also misbranded where its labeling failed to bear information required

under the FDCA, and if this required language was not in the English language. 21 U.S.C. § 352(f)(1).

9. In addition, to ensure that prescription drugs in particular move through a proper, safe, and transparent supply chain, the FDCA required that persons engaged in the wholesale distribution in interstate commerce of prescription drugs in a State be licensed by the State. 21 U.S.C. § 353(e)(2)(A). For example, FDA regulations for wholesale distributors – those shipping prescription drugs to other than the consumer or patient – provide: (a) wholesale distributors are subject to strict storage and handling requirements, and must at a minimum keep records tracking the distribution of prescription drugs. Facilities, for example, must provide adequate lighting, ventilation, temperature, humidity, and security; must quarantine damaged, deteriorated, misbranded, or adulterated prescription drugs; and must store prescription drugs “at appropriate temperatures and under appropriate conditions in accordance with requirements”; (b) to obtain licenses, wholesale distributors must disclose the contact persons for all facilities used for storage, handling, and distribution of prescription drugs; (c) wholesale distributors who were not the manufacturer or an authorized distributor of record were required to provide to the person who received the drug, before each wholesale distribution, a statement identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction). This is known as the “pedigree” requirement.

10. Defendant HANOCH DAVID STEIN agrees that he knew that neither he nor any of his co-defendants and co-conspirators were licensed wholesale distributors permitted to sell prescription drugs within the United States and in the Commonwealth of Virginia, and so were not regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices in the United States. To evade law enforcement detection, neither STEIN nor any of

the defendants and co-conspirators adhered to appropriate storage and handling, record-keeping, and reporting requirements as would be required of lawful and licensed wholesalers in the United States. For example:

a. Facilities used by members of the conspiracy for the storage and handling of prescription drugs and devices consisted of unregistered commercial mailboxes at United Parcel Service (“UPS”) and other commercial vendors, residential backyards and porches, basement rooms, garages, kitchen fridges and freezers, and personal residences which did not have adequate lighting, ventilation, temperature, humidity, and security as required for the safe handling and storage of prescription drugs and devices. Members of the conspiracy—who did not have any formal training or experience in handling prescription drugs and devices—did not properly quarantine damaged, deteriorated, misbranded, or adulterated prescription drugs and in some cases caused them to be shipped to United States doctors and medical practices.

b. Shipping methods used by members of the conspiracy were designed to evade law enforcement detection, and so often took weeks to arrive in the United States from abroad. Instead of using dry ice or other means of appropriately packing prescription drugs and devices and shipping them by overnight mail, members of the conspiracy often used ice packs and cooling packs, Styrofoam boxes, and other picnic cold packs from Walmart or other stores for shipment over longer periods of time, and often failed to keep cold chain prescription drugs at the required temperatures altogether. As a result, prescription drugs and devices required to be kept at low and specific temperatures routinely arrived warm, wet, or otherwise damaged.

c. Members of the conspiracy, not being regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices in the United States, did not

keep the required records and reports as required of lawful and licensed wholesalers in the United States.

Defendant Stein's Role and Participation

11. For the duration of the charged conspiracy, defendant HANOCH DAVID STEIN served as a key individual drop shipper in Baltimore, Maryland, on behalf of the TC MEDICAL GROUP and SB MEDICAL INC. organization. STEIN's role as a drop shipper was to receive, repack, and re-ship misbranded prescription drugs and devices to customers throughout the United States to give the false impression that TC MEDICAL GROUP and SB MEDICAL INC. were based in the United States. STEIN often used, among other false names, the false name "Albert Simmins" or "Albert Simmons" in connection with his activities.

12. In particular, shipping records, emails gathered during the course of the investigation, and surveillance would establish that defendant HANOCH DAVID STEIN used his residence in Baltimore as a collection point to receive large quantities of misbranded prescription drugs and devices from abroad or through yet other re-shipping locations in the United States, including Windsor Mills, Maryland, A.T.'s residence in Baltimore, Maryland, other drop ship locations in New Jersey operated by co-conspirators R.R., M.R., E.M., S.M., and other places.

13. In particular, defendant HANOCH DAVID STEIN opened a mailbox located at 2505 Lord Baltimore Drive in Baltimore, Maryland, on November 2, 2011, for the purpose of receiving packages of non-FDA approved prescription drugs and devices from foreign sources which bore fraudulent customs declarations in order to smuggle them into the United States. The misbranded drugs and devices were intended for the illegal re-distribution within the United States. Law enforcement officers would confirm from emails, physical shipments, and other

evidence that, for example, on or about December 30, 2014, this mailbox contained evidence related to the illegal smuggling and distribution of misbranded prescription drugs and devices by the TC MEDICAL GROUP and SB MEDICAL INC., as follows:

Description of package addressed to STEIN mailbox	Actual Contents
Box from TC DIRECT from Canada declared as "personal medical supply" valued at \$50.00	10 boxes of Synvisc
Box from TC DIRECT from Canada declared as "personal medical supply" valued at \$50.00	5 boxes of Synvisc
Box from United Kingdom addressed to "Albert Simmons" declared as "cosmetic samples" valued at \$31.25	8 boxes of Botox
Box from United Kingdom addressed to "Albert Simmons" declared as "cosmetic samples" valued at \$250.00	20 boxes of Botox
Box sent from Lakewood, New Jersey, addressed to "Albert Simmons"	35 boxes of Botox

14. From his residence, defendant HANOCH DAVID STEIN would next receive orders for prescription drugs and devices from other members of the conspiracy, including co-defendants TZVI LEXIER, DAVID E. BURKE, ASAF AKIVA IBRAHIMIAN, and REUVEN MIRLIS, package misbranded prescription drugs and devices for further shipment to United States doctors and medical practices, and arrange for UPS to pick up and ship these pharmaceutical products multiple times a week. For example, boxes which had been picked up from defendant HANOCH DAVID STEIN's home and turned over by UPS on December 23, 2014 contained the following:

Description of package picked up by UPS from STEIN's home	Contents
Box from TC MEDICAL addressed to customer in Albuquerque, New Mexico	1 box of Botox (100 units)
Box from TC MEDICAL addressed to customer in Denver, Colorado	1 box of Botox (100 units)
Box from TC MEDICAL addressed to customer in Santa Rose, California	1 box of Botox (100 units)
Box from TC MEDICAL addressed to customer in Centennial, Colorado	1 box of Juvederm, 2 boxes of Botox (100 units)
Box from TC MEDICAL addressed to customer in Hallandale,	6 boxes of Restylane, 1 box of

Florida	Botox (100 units)
Box from TC MEDICAL addressed to customer in Harwich, Massachusetts	2 boxes of Juvederm, 2 boxes of Botox (100 units)
Box from TC MEDICAL addressed to customer in Phoenix, Arizona	3 boxes of Juvederm, 5 boxes of Botox (100 units)
Box from TC MEDICAL addressed to customer in Nacogdoches, Texas	6 boxes of Euflexxa
Box from TC MEDICAL addressed to customer in Phoenix, Arizona	3 boxes of Radiesse, 5 boxes of Juvederm

Additionally, invoices received from UPS for account # 6R173Y—the account of TC MEDICAL GROUP—show that account as being registered to defendant HANOCH DAVID STEIN's home.

15. The government would also introduce testimony, evidence, and records from shipments of misbranded prescription drugs and devices from the TC MEDICAL GROUP to locations within the Eastern District of Virginia, which defendant HANOCH DAVID STEIN helped deliver. For example, on or about April 4, 2012, defendant HANOCH DAVID STEIN, together with co-defendants TC MEDICAL GROUP, SB MEDICAL INC., and DAVID E. BURKE, and with the intent to defraud and mislead, introduced, delivered for introduction, and caused and aided and abetted the introduction and delivery for introduction into interstate commerce, into the Eastern District of Virginia to a medical practice in Chantilly, Virginia, in the Eastern District of Virginia, two boxes of misbranded Botox.

16. In addition, the government would introduce evidence of undercover buys of misbranded drugs and devices from the TC MEDICAL GROUP, which defendant HANOCH DAVID STEIN helped deliver into the Eastern District of Virginia using UPS. Specifically, defendant HANOCH DAVID STEIN helped deliver the following misbranded prescription drugs and devices into the Eastern District of Virginia on the following dates:

2/27/14	2 boxes of Botox and one box of Juvederm sold and transported to Leesburg,
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	Virginia
3/12/14	2 boxes of Botox, one box of Juvederm, and one box of Restylane sold and transported to Leesburg, Virginia
4/2/14	3 boxes of Botox sold and transported to Leesburg, Virginia
4/25/14	2 boxes of Botox and one box of Juvederm sold and transported to Leesburg, Virginia
7/11/14	3 boxes of Botox sold and transported to Leesburg, Virginia

17. Law enforcement officers would testify that, based on surveillance of defendant HANOCH DAVID STEIN's home, a UPS truck has been arriving in the evenings on Mondays, Tuesdays and Wednesdays, to collect multiple boxes from this location. These boxes are consistent in shape in size with those parcels order by the government in an undercover capacity that contained foreign, misbranded drugs and medical devices. For example, during surveillance on June 9, 2014, a blue tarp was observed covering part of the deck located at the rear of the defendant HANOCH DAVID STEIN's home. Behind this tarp, white Styrofoam coolers were observed stacked against the railing. The observed coolers were identical in size and shape to the ones used to ship Botox, Juvederm and Restylane that were obtained during undercover purchases in this investigation.

18. According to bank and email records, from at least June 2012 through at least August 2014, defendant HANOCH DAVID STEIN received at least \$174,015.12 as payments for providing "Warehouse Services" for the TC MEDICAL GROUP and SB MEDICAL INC. organization.

19. In addition, members of the conspiracy regularly communicated with each other via email about the foreign acquisition, illegal importation, and sale of misbranded prescription drugs and devices in the United States. Specifically, defendant HANOCH DAVID STEIN regularly communicated by email with other members of the conspiracy, including co-defendants

DAVID E. BURKE, TZVI LEXIER, ASAF AKIVA IBRAHIMIAN, and REUVEN MIRLIS, as well as co-conspirators including R.L. and S.R., co-conspirators in Germany, including C.G., and co-conspirators in the United States, including A.T. in Baltimore, Maryland; R.R. and M.R. in Lakewood, New Jersey; S.M. and E.M. in Edison, New Jersey; and A.B. in Boynton Beach, Florida. For example:

a. Defendant HANOCH DAVID STEIN, together with co-conspirator A.T., shared responsibility for emails sent to and from shipmed123@gmail.com, as email headers and records from the Internet Service Provider would confirm. The government would also introduce evidence that A.T. received packages of misbranded prescription drugs and devices at his home in Baltimore, Maryland, and would physically deliver packages to defendant HANOCH DAVID STEIN's home for further re-packing and re-shipment to United States customers. The shipmed123@gmail.com email address was used in Baltimore, Maryland, to coordinate the smuggling and shipping of misbranded prescription drugs and devices to United States customers, including customers in the Eastern District of Virginia, and to inform other members of the conspiracy about inventory and other supply issues. Other email addresses used by members of the conspiracy included jerseywarehouse123@gmail.com used by R.R. and M.R. in Lakewood, New Jersey, and shippingguru11@gmail.com used by E.M. and S.M. in Edison, New Jersey, and Greenwich, Connecticut. In addition, A.B. worked as a drop shipper based in Boynton Beach, Florida, using shipping@tcmedicalgroup.com.

b. On April 28, 2011, co-defendant TZVI LEXIER forwarded to defendant HANOCH DAVID STEIN a customer email which stated: "We received the botox this a.m. at 10:30, my only concern is that the ice packs were completely thawed and it wasn't even a little

cold. I've never received a shipment of refrigerated product that warm before and I am concerned whether it is useable. We'll try it, but in the future will need to be packaged better."

c. On May 31, 2011, defendant HANOCH DAVID STEIN informed co-defendants TZVI LEXIER and DAVID E. BURKE: "customers have been complaining about the Botox arriving warm. Storing and purchasing dry ice is complicated, also it freezes the good... Up until now I have been using smaller coolers (with a thinner wall) and smaller ice packs (to save on shipping)."

d. On June 2, 2011, defendant HANOCH DAVID STEIN informed a co-conspirator and co-defendant TZVI LEXIER: "We received 30 boxes of Hyalgan. (FYI it is all in Spanish no English) Should I now ship out orders #5 and #6 from yesterday?" The co-conspirator responded: "Let me check David as I don't know if the all Spanish is an issue."

e. On July 12, 2011, defendant HANOCH DAVID STEIN informed co-defendant TZVI LEXIER and co-conspirator R.L.: "I need to order supplies ASAP. I already stopped using the wrap that I use in the coolers to keep the botox cold."

f. On September 15, 2011, co-defendant DAVID E. BURKE instructed defendant HANOCH DAVID STEIN to "ship 6 turkish 8 juvederm" to a doctor in Utah.

g. On December 12, 2011, defendant HANOCH DAVID STEIN informed co-defendant TZVI LEXIER that: "3 Turkish from [a doctor] FYI They were sent in an envelope (warm) They are taped together. Let me know if you can sell them and who I should send them to." A co-conspirator responded: "david, please put them in the fridge - we are selling them as normal."

h. On January 26, 2012, defendant HANOCH DAVID STEIN emailed to co-defendant TZVI LEXIER photos of drugs and devices including Supartz labeled "INTENDED

FOR PHILIPPINE USE ONLY,” Aclasta, Bonviva, Orenica, Remicade, and Zometa boxes labeled in Turkish, and Prolia labeled in French.

i. On May 4, 2012, co-conspirator S.R., using the false name “David Robertson,” emailed to defendant HANOCH DAVID STEIN information related to a large order of Orthovisc by a customer in the United States.

j. On June 26, 2012, co-conspirator S.R. emailed defendant HANOCH DAVID STEIN the false name “Mike Roth” at an address in Lakewood, New Jersey, which was the residence of co-conspirators R.R. and M.R.

k. On September 7, 2012, a co-conspirator emailed defendant HANOCH DAVID STEIN and co-conspirator A.T. with instructions on how to keep inventory of misbranded prescription drugs and devices. Co-conspirator R.L. responded, “This is excellent.”

l. On October 3, 2012, co-conspirator S.R. emailed defendant HANOCH DAVID STEIN asking for a shipment of 50 boxes of Euflexxa to a customer in Vermont.

m. On October 25, 2012, co-defendant DAVID E. BURKE emailed co-conspirators, including defendant HANOCH DAVID STEIN with instructions to “please make sure that these synvisc ones are clean meaning that they don’t have the Netherlands symbol on it.”

n. On January 25, 2013, co-defendant REUVEN MIRLIS emailed defendant HANOCH DAVID STEIN stating, “Hey its Daniel, I just wanna confirm that the 4 synvisc classic to Arizona will be shipped out today to be arriving on Monday.”

o. On February 20, 2013, co-conspirators including defendant HANOCH DAVID STEIN emailed each other in emails with the subject line, “inventory transfer” about Botox shipments to various drop locations. A co-conspirator emailed STEIN asking, “David, Are

you sure there wasn't 7 botox? Moe how many did you send?" STEIN from shipmed123@gmail.com responded, "I only got 6 David. jerseywarehouse123@gmail.com, the email account used by co-conspiring drop shippers R.R. and M.R. responded, "No I'm positive I sent 7. One bottle of Botox was wrapped in bubble wrap as I mentioned."

p. On April 16, 2013, co-conspirator drop shipper A.T. emailed to shipmed123@gmail.com, the email account used by defendant HANOCH DAVID STEIN a message related to a shipment of Radiesse to a customer in Georgia.

q. On July 8, 2013, co-defendant ASAF AKIVA IBRAHIMIAN emailed defendant HANOCH DAVID STEIN with instructions to schedule a pickup of product from a customer in Louisiana, and to create a return label made to an address in Lakewood, New Jersey, the address of co-conspirator drop shippers R.R. and M.R.

r. On August 27, 2013, defendant HANOCH DAVID STEIN emailed co-conspirator R.L. under the subject line "Invoice" and stated: "Hi Dr. Lexier, Please make the check out to David Stein." Attached to the email was an invoice from the defendant's home. The invoice was for warehouse fees and rent in the amount of \$5,535.00. It also listed a total of 349 packages sent and the dates they were sent. On March 24, 2014, another email was sent from shipmed123@gmail.com with the subject line "Invoice". The message stated: "Hi, Please send one check per invoice. Please make payable to David Stein. Please express to: David stein [listing defendant HANOCH DAVID STEIN's home address] USA." Attached to the email were five monthly invoices. The invoices reflected over a thousand orders from October 2013 through February 2014.

s. On September 2, 2013, co-defendant DAVID E. BURKE emailed to shippingguru11@gmail.com, the email address used by co-conspirator drop shippers E.M. and

S.M., with instructions to send shipments to defendant HANOCH DAVID STEIN under the false name of “Albert Simmons.”

t. On September 9, 2013, co-defendant DAVID E. BURKE and shippinggurull@gmail.com, the email account used by co-conspirators E.M. and S.M., exchanged emails under the subject line, “products arrived please ship to Baltimore.”

u. On September 11, 2013, defendant HANOCH DAVID STEIN informed another member of the conspiracy that, “We don’t carry the ortho in Baltimore.” STEIN sent the email to jerseywarehouse123@gmail.com, an email account used by co-conspirators R.R. and M.R., which was used by the TC MEDICAL GROUP and SB MEDICAL INC. and its affiliates as a drop location for misbranded drugs and devices in the United States.

v. On December 13, 2013, co-defendant DAVID E. BURKE emailed shippinggurull@gmail.com to ask if any shipments had been sent to Baltimore. Co-conspirator E.M. responded, “Yes. 2 pkgs.”

20. The government would further introduce evidence showing that members of the conspiracy, including defendant HANOCH DAVID STEIN, received letters, including on or about November 2, 2011 and December 8, 2011, from the FDA noting that certain shipments of drugs and devices which had been imported had been detained for being unapproved by the FDA. Despite notice of these letters, members of the conspiracy affiliated with the TC MEDICAL GROUP and SB MEDICAL INC. continued to smuggle and sell misbranded prescription drugs and devices within the United States.

21. In addition, from at least October 2011 through at least October 2014, members of the conspiracy did knowingly combine, conspire, and agree with each other and with other persons to commit money laundering, which was to transport, transmit and transfer and attempt

to transport, transmit and transfer a monetary instrument and funds from a place in the United States to and through a place outside the United States with the intent to promote the carrying on of specified unlawful activity, which consisted of fraudulently and knowingly import and bring into the United States merchandise contrary to law, and receive, conceal, buy, sell, or in any manner facilitate the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law.

22. Defendant HANOCH DAVID STEIN agrees that he and co-defendants moved the proceeds from the sale of misbranded prescription drugs and devices which had been imported contrary to law from the United States to bank accounts in Canada in two main ways. First, the defendants used credit card payment systems and processors to transfer proceeds from the United States to Canada. In this way, members of the conspiracy caused at least \$14,786,900 to be transferred from payment card transactions, including VISA and MasterCard into the bank account of defendant SB MEDICAL INC. in Canada. Payment card transactions of VISA were conducted through servers in Ashburn, Virginia, in the Eastern District of Virginia. Second, co-conspirator drop shippers based in the United States received payment checks by mail, bundled them, and forwarded them to Canada to be deposited into bank accounts, all to give the false impression to customers including doctors and medical practices that the defendants operated legally in the United States.

23. Once the funds were in the bank account of defendant SB MEDICAL INC., the co-defendants caused further financial transactions to be made in furtherance of the conspiracy, including:

a. Payments amounting to millions of dollars to foreign co-conspirator suppliers to obtain supplies of prescription drugs and devices intended for the illegal importation into the United States;

b. Payments amounting to millions of dollars to co-conspirator salespersons in the United States and Canada, including co-defendants ASAF AKIVA IBRAHIMIAN, REUVEN MIRLIS, and DAVID E. BURKE, representing commission payments for the illegal importation and sale of misbranded prescription drugs and devices within the United States on behalf of TC MEDICAL GROUP and SB MEDICAL INC.

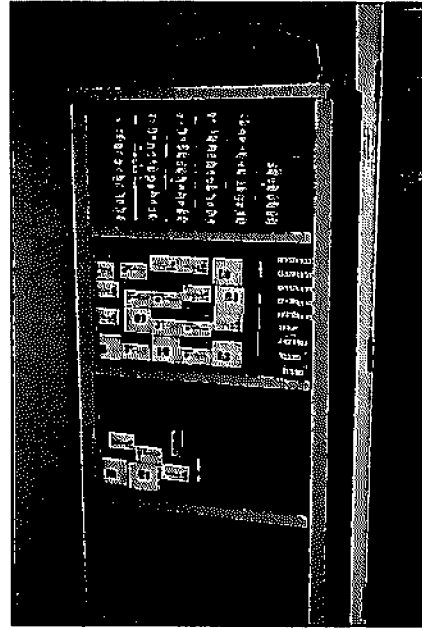
c. Payments amounting to hundreds of thousands of dollars to co-conspirator drop shippers in the United States, including defendant HANOCH DAVID STEIN, representing payments for receiving, repacking, and resending misbranded prescription drugs and devices to other customers or locations within the United States. Bank records would show that STEIN received payments from Scotia Bank account ending in 0915 registered to defendant SB MEDICAL INC. located at 340 College Street, Ste. 210, Toronto, ON M5T 3A9 which were deposited into STEIN's account.

d. Distributions amounting to hundreds of thousands of dollars to co-conspirator and principal of TC MEDICAL GROUP and SB MEDICAL INC., defendant TZVI LEXIER.

24. On December 23, 2014, during a search of defendant HANOCH DAVID STEIN's home in Maryland, law enforcement officers recovered evidence that the TC MEDICAL GROUP, SB MEDICAL INC., and its employees and agents were engaged in the smuggling and distribution of misbranded prescription drugs and devices, and were also engaged in the unlawful and unlicensed wholesale distribution of prescription drugs in the Eastern District

of Virginia and elsewhere. STEIN admitted that the prescription drugs and devices in the home were attributable to him and not that of his roommates. In addition, law enforcement officers recovered the following and as depicted:

- a. UPS shipping labels for defendant TC MEDICAL GROUP, invoices for SB MEDICAL INC.;
- b. Boxes of misbranded prescription drugs and devices, including Radiesse, Juvederm, Botox, Belotero (injectable prescription wrinkle filler), Sculptra (injectable prescription wrinkle filler), Xeomin (injectable prescription wrinkle filler), Orthovisc, Euflexxa, Orencia, Synvisc, Restylane, Actemra, Dysport, Prolia;
- c. Mislabeled customs declaration labels taken from shipped boxes;
- d. Envelopes, boxes, packing materials, Styrofoam coolers and ice packs;
- e. Boxes addressed to "Albert Simmins," the false name used by defendant HANOCH DAVID STEIN, boxes addressed to A.T., Baltimore-based co-conspirator drop shipper.



25. The statement of facts includes those facts necessary to support the defendant's guilty plea. It does not include each and every fact known to the defendant or to the government and it is not intended to be a full enumeration of all of the facts surrounding the defendant's case.

26. The actions of the defendant, as recounted above, were in all respects knowing, voluntary, and intentional, and were not committed by mistake, accident or other innocent reason.

27. The defendant waives any rights under Fed. R. Crim. P. 11(f), Fed. R. Evid. 410, the United States Constitution, and any federal statute or rule in objecting to the admissibility of the Statement of Facts in any such proceeding.


Dana J. Boente
United States Attorney

By: 

Alexander T.H. Nguyen
Jay V. Prabhu
Kellen S. Dwyer
Assistant United States Attorneys

Defendant's Signature: After consulting with my attorney, I hereby stipulate that the above Statement of Facts is true and accurate and that had the matter proceeded to trial, the United States would have proved the same beyond a reasonable doubt.


Date: 5/5, 2015



Hanoch David Stein
Defendant

Defense Counsel Signature: I am Hanoch David Stein's attorney. I have carefully reviewed the above Statement of Facts with him. To my knowledge, his decision to stipulate to these facts is an informed and voluntary one.

Date: 5/5, 2015



Ari Casper, Esq.
Counsel for the Defendant